Translation

PATENT COOPERATION TREATY

PCT/JP2003/011806

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 03-063-PCT	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/JP2003/011806	International filing date (*day/month/year*) 17 September 2003 (17.09.2003)	Priority date (*day/month/year*) 19 September 2002 (19.09.2002)
International Patent Classification (IPC) or national classification and IPC C07D 405/12, A61K 31/4525, A61P 25/00, 25/04, 25/22, 25/24, 25/28, 43/00		
Applicant SUMITOMO CHEMICAL COMPANY, LIMITED		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

   a. ☐ *(sent to the applicant and to the International Bureau)* a total of _____ sheets, as follows:

      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

- ☒ Box No. I Basis of the report
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
17 February 2004 (17.02.2004)	18 August 2004 (18.08.2004)
Name and mailing address of the IPEA/JP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP2003/011806

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language _____, which is language of a translation furnished for the purpose of:

☐ international search (under Rules 12.3 and 23.1(b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

☒ The international application as originally filed/furnished

☐ the description:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the claims:

pages _____, as originally filed/furnished

pages* _____, as amended (together with any statement) under Article 19

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ the drawings:

pages _____, as originally filed/furnished

pages* _____ received by this Authority on _____

pages* _____ received by this Authority on _____

☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/figs _____

☐ the sequence listing *(specify)*: _____

☐ any table(s) related to sequence listing *(specify)*: _____

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/JP03/11806

Box No. V **Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

Novelty (N)	Claims	1-7	YES
	Claims	8, 9	NO
Inventive step (IS)	Claims	1-7	YES
	Claims	8, 9	NO
Industrial applicability (IA)	Claims	1-9	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

Document 1: EP 223403 A2 (Beecham Group PLC) May 27, 1987
Document 2: EP 812827 A1 (Sumika Fine Chemicals Co., Ltd.) December 17, 1997

Document 1 cited in the international search report (see Claim 1, etc.) states that hemihydrate crystals can be obtained by crystallization or recrystallization of paroxetine hydrochloride from a solvent system that contains water (see page 4, lines 16 to 20).

Document 2 describes a process for obtaining paroxetine hydrochloride by reacting (3S4R)-trans-1-tert-butoxycarbonyl-4-(4-fluorophenyl)-3-[3,4-methylenedioxyphenyl] oxymethyl] piperidine with hydrogen chloride in isopropanol (see Claim 11, etc.)

oClaims 1-7

Documents 1 and 2 above neither describe nor suggest the inventions of claims 1-7, and therefore these inventions are novel and involve an inventive step.

oClaims 8 and 9

Paroxetine hydrochloride hydrate specified by the process of its manufacture is described in the above claims of this application, but the paroxetine hydrochloride hydrate prepared by the process specified in the above claims and the paroxetine hydrochloride prepared by the process described in document 1 are one and the same, and are thus indistinguishable.

As a result, the inventions of claims 8 and 9 lack novelty and an inventive step with respect to document 1 above.

In a written reply dated August 5, 2004, the applicant asserts: "the paroxetine hydrochloride hydrate described in claims 8 and 9 is produced by a process that is different from the process for producing the paroxetine hydrochloride hydrate described in document 1 and can thus be understood to be novel and to involve an inventive step with respect to document 1 (note: typographical error in applicant's assertion corrected)."

However, when an inventive "substance" is identical to a "substance" known from prior art, it cannot be considered to be novel or to involve an inventive step even if the process for producing is different. Because the paroxetine hydrochloride hydrate in the claims of this application and the crystalline paroxetine hydrochloride hydrate described in document 1 cannot be considered to differ as "substances," this examination cannot recognize that the inventions of the above claims of this application have novelty and an inventive step.